19. 510(k) Summary

K042246

510(k) SUMMARY – Safety and Effectiveness

Multi Drip™ Infusion Catheter

1. Submitters Name:

Advanced Infusion, Inc.
6200 South McClintock #6
Tempe, AZ 85283
(480) 768-9747 (Phone)
(480) 894-5288 (Fax)
Contact: Dr. Reese
Date Prepared: March 26, 2004

2. Name of Device:

Trade Name: *Multi Drip*™ Infusion Catheter
Common Name: Infusion Catheter
Classification Name: Pump, Infusion, Elastomeric

3. Predicate Device:

The proposed device, the *Multi Drip*™ Infusion Catheter, claims substantial equivalence to AI's currently marketed *Alpha Cath* Infusion Catheter (K021964) in function, design, materials of construction, operation, and intended use. Both catheters are for use with the AI *Alpha Infusion Pump* (K021964).

In addition, the *Multi Drip*™ Infusion Catheter claims substantial equivalence to the I-Flow Soaker multiple port Catheter (K994374) and the Stryker (McKinley) ExFen multiple port Catheter (K033039) in regards to the function, overall design of the distal end of the catheter, and intended use.

4. Description of Device:

The *Multi Drip*™ Infusion Catheter is designed to be used with the *Alpha Infusion Pump* (K021964) to deliver a continuous infusion of medication to a patient at a predetermined flow rate. It is a sterile, non-pyrogenic, single use device for use in the hospital or by an ambulatory patient.

Except for the size of the exit ports and the closed distal end of the catheter, the *Multi Drip*™ Infusion Catheter is identical in construction and operation to the previously cleared *Alpha Cath* Infusion Catheter series (K021964).

Like the *Alpha Cath* Infusion Catheter, the proximal end of the *Multi Drip*™ Infusion Catheter has a stainless steel needle attached to it for insertion of the catheter into the outflow septum of the *Alpha Infusion Pump.* The flow rate of the fluid delivered from the

Alpha Infusion Pump through the catheter is determined by the preset delivery pressure of the pump and the internal diameter and length of the micro-bore PVC tubing forming the catheter. The *Multi Drip*™ Infusion Catheters are available in a range of lengths and flow rates similar to those of the *Alpha Cath* Infusion Catheters. Both catheter series are packaged in individual Tyvek pouches and sterilized by gamma irradiation.

5. Statement of Intended Use

The *Multi Drip*™ Infusion Catheter is a single-use, short duration catheter intended for use with the *Alpha Infusion Pump* for the continuous infusion of medication directly into an intraoperative site for postoperative pain management. Infusions may also be administered percutaneously.

6. Comparison to Predicate

The proposed device, the *Multi Drip*™ Infusion Catheter, claims substantial equivalence to Advanced Infusion's currently marketed *Alpha Cath* Infusion Catheter (K021964) in function, design, materials of construction, operation, and intended use. Both catheters are for use with the *Alpha Infusion Pump* (K021964). Both catheters are constructed of the same material, have the same outer diameter and length, have the same internal diameter that functions as a flow restrictor, have a needle attached to the proximal end for insertion of the catheter into the *Alpha Infusion Pump,* and have ports along the distal end of the catheter. The only differences between the two catheters is that the end of the *Alpha Cath* Infusion Catheter is open while the end of the *Multi Drip*™ Infusion Catheter is closed, and the ports on the *Alpha Cath* Infusion Catheter are axial slits while the ports on the *Multi Drip*™ Infusion Catheter are tiny round holes.

If the distal end of the *Alpha Cath* Infusion Catheter should become blocked during use, the medication will continue to flow out of the axial slit ports along the side of the distal end of the catheter. In this condition, the *Alpha Cath* Infusion Catheter functions in exactly the same way as the *Multi Drip*™ Infusion Catheter. The *Multi Drip*™ Infusion Catheter is manufacture with the distal end of the catheter closed, so that flow will only occur through the ports along the side of the distal end of the catheter. Therefore, the *Multi Drip*™ Infusion Catheter is substantially equivalent to the *Alpha Cath* Infusion Catheter in function, design, materials of construction, operation, and intended use.

In addition, the *Multi Drip*™ Infusion Catheter is substantial equivalence to the I-Flow Soaker Catheter (K994374) and the Stryker ExFen Catheter (K033039) in regards to function, design of the distal end of the catheter, and intended use. The function of the Soaker Catheter, the ExFen Catheter, and the *Multi Drip*™ Infusion Catheter, is to cause flow to occur through the side ports along the distal end of the catheters. This is accomplished by closing off the end of the catheters which causes flow to occur only through the side ports. The length of the distal portion of the catheter having ports is either 6.5 cm or 12.5 cm for all three style catheters.

The I-Flow Soaker Catheter has 0.13 mm diameter holes spaced approximately every 0.5 cm along the distal portion of the catheter. In order to obtain flow through all the holes, a cellulose hollow fiber filter is placed inside the distal end of the catheter. As fluid seeps

through the filter, it flows out the side port holes. However, during actual use, only a portion of the holes actually flow.

The Stryker ExFen Catheter has 0.13 mm diameter holes spaced approximately every 0.4 cm along the distal portion of the catheter. In order to obtain flow through all the holes, a tightly coiled stainless steel spring is placed inside the distal end of the catheter. As fluid seeps through the coils of the spring, it flows out the side port holes. However, during actual use, only a portion of the holes actually flow.

The Advanced Infusion *Multi Drip*™ Infusion Catheter has six 0.05 mm diameter holes spaced along the distal portion of the catheter. Spacing is either 1 cm or 2 cm depending on the length of the infusion portion of the catheter. In order to obtain flow through all the holes, the diameter and quantity of the holes is balanced to the flow rate through the catheter. During testing, flow was achieved through at least 4 of the 6 holes present in all catheters.

The *Multi Drip*™ Infusion Catheter is also substantially equivalent in function, overall design of the distal end, and intended use to the I-Flow Soaker Catheter and the Stryker ExFen Catheter.

7. Performance Data (summary)

The *Multi Drip*™ Infusion Catheter is identical in materials and construction to the *Alpha Cath* Infusion Catheter except for the port configuration at the end of the catheter. The physical specifications and performance of the *Multi Drip*™ and *Alpha Cath* Infusion Catheter are identical.

Catheter Outer Diameter:	2 Fr. (0.6mm)
Catheter Length:	60 cm & 120 cm, ±10%
Catheter Breaking Strength:	approximately 2.5 pounds
Catheter to Needle Bond Strength:	catheter breaks, does not pull apart

Multi Drip™ Infusion Catheters are 100% tested for flow rate, as are the *Alpha Cath* Infusion Catheters, prior to release. The product flow rate accuracy is established at ±15% of the indicated flow rate.

The *Multi Drip*™ Infusion Catheter is equivalent in design of the infusion portion of the catheter to the I-Flow Soaker and Stryker ExFen catheters. All three catheters have a closed off end, have a 6.5 cm or 12.5 cm infusion portion along the distal end of the catheter, and have round holes spaced along the entire length of the infusion portion.

The I-Flow Soaker Catheter uses a hollow fiber filter to distribute fluid to all of its ports. The Stryker ExFen Catheter uses a coiled stainless steel spring to distribute fluid to all of its ports. However, during actual use, only a portion of the ports in either catheter actually flowed.

The *Multi Drip*™ Infusion Catheter uses a few small diameter holes to distribute fluid flow along the infusion portion of the catheter. The diameter of these ports in the *Multi Drip*™

Infusion Catheter was selected so that at least four out of the six ports flowed. The performance of the infusion portion of these three style catheters was substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Advanced Infusion, Incorporated
C/O Mr. Neil Devine, Jr.
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K042246
Trade/Device Name: *Multi Drip*™ Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

20. Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K042246

Device Name: *Multi Drip*™ Infusion Catheter

Indications for Use:

The *Multi Drip*™ Infusion Catheter is a single-use, short duration catheter intended for use with the *Alpha Infusion Pump* for the continuous infusion of medication directly into an intraoperative site for postoperative pain management. Infusions may also be administered percutaneously.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042246